Section 3
Data Quality Objectives

The DQO process, based on scientific methods, is a series of planning steps that are designed to ensure that the type, quantity, and quality of environmental data used in decision-making are appropriate for the intended purpose. EPA has issued guidelines to help data users develop site-specific DQOs (EPA 2006a). These guidelines were followed for the development of the DQOs presented in this section.

The DQO process specifies project decisions, the data quality required to support those decisions, specific data types needed, data collection requirements, and analytical techniques necessary to generate the specified data quality. The process also ensures that the resources required to generate the data are justified. The DQO process consists of seven steps; output from each step influences the choices that will be made later in the process. These steps include:

1. State the problem
2. Identify the decision
3. Identify the inputs to the decision
4. Define the study boundaries
5. Develop a decision rule
6. Specify tolerable limits on decision errors
7. Optimize the design

3.1 Step 1 – State the Problem

The purpose of this step is to describe the problem to be studied so that the focus of the investigation will be unambiguous.

As determined by previous investigations conducted at the Libby Superfund Site, LA is present in multiple environmental media in Libby and OU1 including: indoor air, outdoor ambient air, indoor dust, vermiculite insulation, and soils. As a result, current and future receptors in OU1 may be exposed to LA, and these exposures may pose a risk of cancer and/or non-cancer effects. EPA is seeking to determine the level of exposure that is occurring specific to receptors in OU1. Based on the assessment of current data available for OU1, the potential exposure pathways requiring additional investigation of media of concern by efforts or evaluations as described by this SAP include:

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- Inhalation of indoor air
- Inhalation of outdoor air near disturbed soils

The other potential exposure pathways, common to other OUs of the Libby Site as well as OU1, will require further evaluation but sample collection specific to OU1 will not be conducted. These pathways will be evaluated as part of the exposure pathway sampling related to OU4 (see CSM for OU4).

3.2 Step 2 – Identify the Decision

This step identifies what questions the investigation will attempt to resolve and what actions may result.

The information EPA is seeking include: 1) levels of LA and/or visual vermiculite in current site soils, and 2) what are the levels of LA encountered during potential exposure pathways at OU1?.

Comment [R1]: Does #2 refer to concentrations in air associated with activities on contaminated soils? What about indoor air?

3.3 Step 3 – Identify the Inputs to the Decision

The purpose of this step is to identify the environmental data that need to be obtained and the measurements that need to be taken to resolve the decision statements.

The information required to answer the study questions is illustrated in Table 3-1. Sampling methods used to collect information required to resolve the study questions will be collected in accordance with the procedures detailed in Section 4 of this SAP.

3.4 Step 4 – Define the Boundaries of the Study

This step specifies the spatial and temporal boundaries of this investigation.

3.4.1 Spatial Bounds

The information gathered to answer the objectives will be collected from within the boundary of OU1 as depicted in Figure 2-3. The vertical extent of the study area will be from the existing ground surface to the bottom of the deepest soil sample and visual inspection points.

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Comment [R2]: What about indoor ABS? spatial bounds would be limited to the search/rescue building.

3.4.2 Temporal Bounds

The temporal boundaries of this investigation include the time from when W.R. Grace conducted operations at the site that resulted in vermiculite being introduced (early 1960s) to the time of this investigation (September/October 2007).

3.5 Step 5 – Develop Decision Rules

The purpose of this step is to describe the method that EPA will use to make final risk management decisions from the data.

At present, risk management decision rules for the site have not yet been defined. It is expected that the decision rule for exposure pathways associated with OU1 will take the

form that the residual cancer and non-cancer risk associated with the reasonable maximum exposure scenario contributed the pathways may not exceed some specified level (either an absolute level or alternatively, some proportion of the total risk).

In the absence of a quantitative decision rule, it is tentatively assumed for the purposes of planning that if risks associated with any exposure pathway under reasonable maximum exposure conditions approach or exceed a cancer risk level of 1E-05 (one in 100,000) or a non-cancer Hazard Quotient (HQ) of 0.1. This assumption is for planning purposes and should not be interpreted as a risk management decision since final risk management decisions will consider the cumulative risk of exposure to multiple exposure pathways. This assumption is used only to support initial efforts to plan the sampling effort.

Comment [R3]: Does this refer to the indoor ABS effort? If so, why doesn't in appear in the previous sections as part of the DQOs?

3.6 Step 6 – Specify Tolerable Limits on Decision Errors

The tolerable limits on decision errors, used to establish performance goals for the data collection design, are specified in this step.

In making risk management decisions with calculated estimates of exposure and risk, two types of decision errors are possible:

- A Type I (false negative) decision error would occur if a risk manager decides that exposure to outdoor ambient air is not of significant health concern, when in fact it is of concern.

Comment [R4]: Not clear why we are referring to outdoor ambient air here. Pls see comments for OU5 SAP.

- A Type II (false positive) decision error would occur if a risk manager decides that exposure to outdoor ambient air is above a level of concern, when in fact it is not.

EPA is most concerned about guarding against the occurrence of Type I errors, since an error of this type may leave humans exposed to unacceptable levels of LA in exposure pathways at OU1. For this reason, it is anticipated that exposure assessment will be based on the best estimate and the 95% upper confidence limit (UCL) of the long-term average concentration of LA in the area being evaluated. Use of the UCL to estimate exposure and risk helps account for limitations in the data, and provides a margin of safety in the risk calculations, ensuring that risk estimates are unlikely to be too low.

EPA is also concerned with the probability of making Type II (false positive) decision errors. Although this type of decision error does not result in unacceptable human exposure, it may result in unnecessary expenditure of resources. For the purposes of this effort, the strategy adopted for controlling Type II errors is to ensure that if the risk estimate based on the 95% UCL is above EPA's level of concern for this pathway, then the UCL is not larger than 3-times the best estimate of the mean. If the 95% UCL is at or above the range that is of potential concern, and the UCL is greater than 3 times the best estimate of the mean, then more data may be needed.

3.7 Step 7 – Optimize the Design for Obtaining Data

This step identifies a resource-effective data collection design for generating data that

are expected to satisfy the DQOs. The data collection design is described in detail in the remaining sections of this SAP and other site documents referenced in Section 4.